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GM plant environmental risk assessment: pros and cons of different approaches

Dr. Hartmut Meyer

ENSSER, Scientific Coordinator

EFSA Consultative Workshop on the Draft Guidance on Selection of Comparators for the Risk Assessment of GM Plants

Concept of Substantial Equivalence in Relation to Risk Assessment

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”Principles for the application of substantial equivalence to the assessment of foods from organisms developed by the application of biotechnology:

1. *If the new or modified food or food component is determined to be substantially equivalent to an existing food, then further safety or nutritional concerns are expected to be insignificant*

OECD 1993a, p. 11-12

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2. *Where a product is determined not to be substantially equivalent, the identified differences should be the focus of further evaluations;*
3. *Where there is no basis for comparison of a new food or food component, ... then the new food or food component should be evaluated on the basis of its own composition and properties.“*

OECD 1993a, p. 11-12

Concept of Familiarity in Relation to Risk Assessment

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”The levels and variation for characteristics in the genetically modified organism must be within the natural range of variation for those characteristics considered in the comparator”

FAO/WHO 1996, p.7

Concept of Familiarity in ERA - Broad Range of Comparators

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"Familiarity comes from the knowledge and experience available for conducting a risk/safety analysis prior to scale-up of any new plant line or crop cultivar in a particular environment. ...

- *... **lines of the crop plant developed with more traditional techniques** ...*
- *... **other plant lines developed by the same technique** ..."*

OECD 1993b, p.28

Application in Food RA - Critique

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*"The concept of substantial equivalence has **never been properly defined**;*

the degree of difference between a natural food and its GM alternative before its 'substance' ceases to be acceptably 'equivalent' is not defined anywhere,

nor has an exact definition been agreed by legislators."

Millstone et al. 1999, p. 525

Application in ERA - Critique

"Hence, the concept of a history of safe use from food safety relates less easily to ERA, in which ***environmental harm*** *is measured. ...*

Second, for ERA, it makes little practical sense for the equivalence limits to be based on the natural variation of extraneous varieties."

Perry et al. 2009, p.68

Concept of Familiarity
- No Recognition in GMO ERA

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Cartagena Protocol on Biosafety:

Concept of Familiarity was introduced in 1996 (BSWG-1), discussed in BSWG-2 and BSWG-3, finally rejected in 1998 (BSWG-4)

Directive 2001/18/EC:

no mentioning of the Concept of Familiarity

Current Legal Approaches in ERA
- Comparision with Parental Organisms

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*"Risks associated with living modified organisms ... should be considered in the context of the risks posed by the **non-modified recipients or parental organisms in the likely potential receiving environment."***

SCBD 2000, Annex III 5.

"In accordance with the precautionary principle, the following general principles should be followed when performing the e.r.a.:

- *identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the **non-modified organism from which it is derived and its use under corresponding situations**; ..."*

EC 2001, Annex II B

Taking up the Criticism

”The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart.”

CAC 2003, para 13

”Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself.”

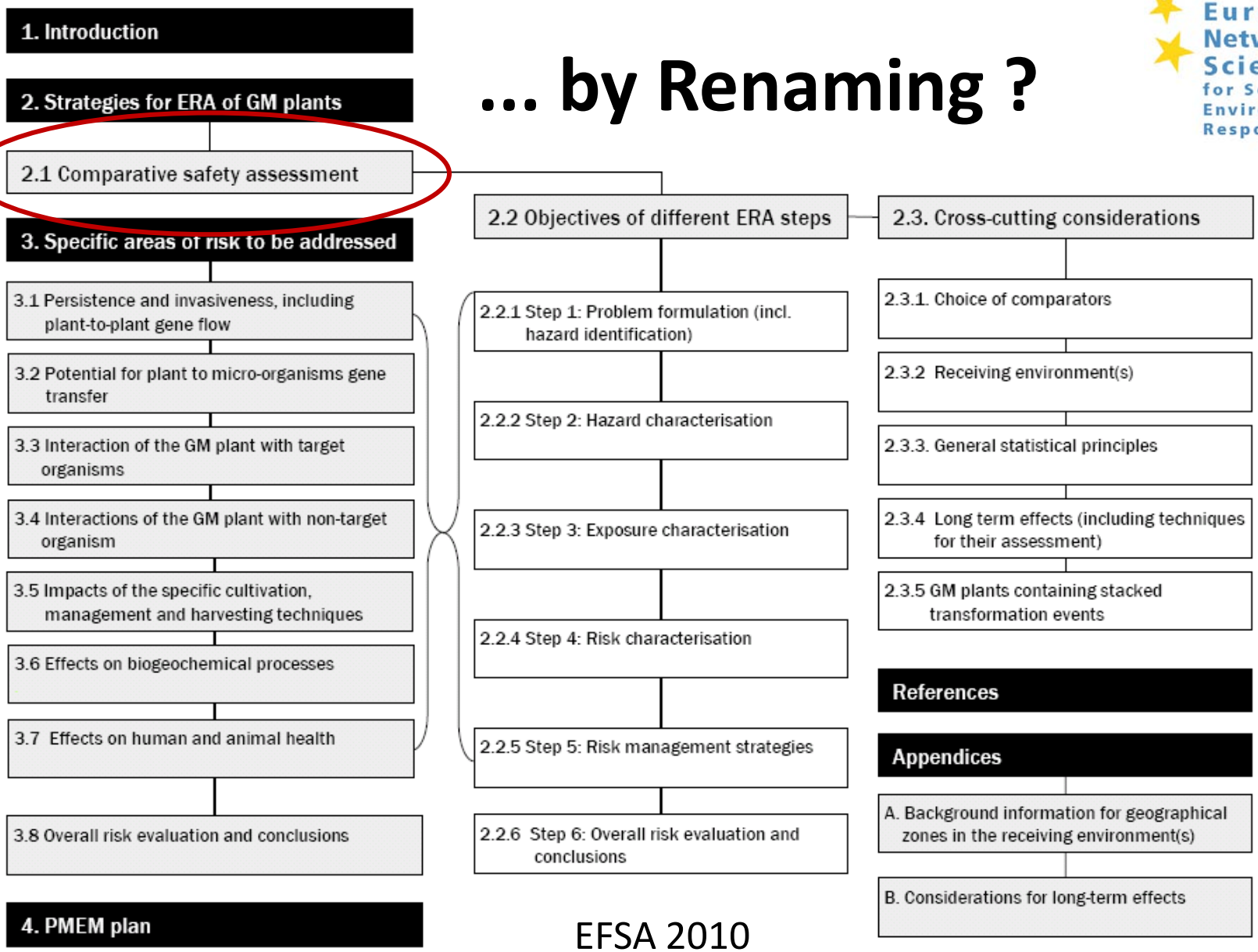
EC 2003, Recital 6

Saving the Concepts ...

*"Statistically significant differences between the GM plant and its appropriate comparators should be assessed specifically with respect to their **biological relevance** and potentially hazardous environmental implications. The outcome of the comparative safety assessment [...] will thus further structure the ERA.*

*.... The underlying assumption of the comparative assessment for GM plants is that the biology of traditionally cultivated plants from which the GM plants have been derived, and the appropriate comparators is well known. To this end the **concept of familiarity** was developed by the OECD."* EFSA 2010

… by Renaming ?



EFSA 2010

Recommendations

- Abandonment of concept of comparative safety assessment and concept of familiarity applied **prior** to ERA
- Strict application of the 2001/18 general principle ”comparison of GMO with parental organisms” **within** ERA
- Development of a risk assessment ”per se” **at least** when there are no appropriate parental organisms

Recommendations

- Establishment of scientific criteria for judging statistically significant differences in unintended effects between the GMO and the biological comparator as biological and ecological irrelevant
- Establishment of scientific criteria for appropriate choice of receiving environments as environmental comparators for the determination of harm

Commissioner John Dalli March 17, 2011

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”Let me draw an example with the strategy for risk assessment, which is often somewhat confusingly termed ’substantial equivalence.’ [...] In actual fact, the ***comparative approach*** *followed in the risk assessment strategy is exactly the opposite.*

A thorough comparison between a GMO and a conventional safe counterpart allows the identification of all the differences created by the genetic modification. [...] ***All these differences are then investigated in detail with respect to possible toxicological, environmental, allergenic or nutritional aspects****. ”*

Dalli 2011

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ENSSER notes with interest that Commissioner Dalli has not used the wording "comparative safety assessment" as suggested as new principle in ERA

ENSSER is determined to engage critically and constructively in the debate on reforming the EU system for GMO and GM food risk assessment.

Thank you!

References

CAC (2003) Guideline for the conduct of food safety assessment of foods derived from recombinant DNA-plants. GL 45-2003

Dalli (2011) GMOs : towards a better, more informed decision-making process

EC (2001) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

EC (2003) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed

EFSA (2010) Guidance on the environmental risk assessment of genetically modified plants

FAO/WHO (1996) Joint FAO/WHO expert consultation on botechnology and food safety

Millstone et al. (1999) Beyond 'substantial equivalence'. Nature 401: 525-526

OECD (1993a) Safety evaluation of foods derived by modern biotechnology – Concepts and principles

OECD (1993b) Safety considerations for biotechnology: Scale-up of crop plants

Perry et al. (2009) Statistical aspects of environmental risk assessment of GM plants for effects on non-target organisms. Environmental Biosafety Research 8: 65–78

SCBD (2000) Cartagena Protocol on Biosafety